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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/896,874	06/29/2001	Lawrence Y. Fang	13615.40USU1	1026

20306 7590 10/22/2003

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EXAMINER

KUMAR, SHAILENDRA

ART UNIT	PAPER NUMBER
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1621

DATE MAILED: 10/22/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/896,874

Applicant(s)

FANG ET AL.

Examiner

SHAILENDRA - KUMAR

Art Unit

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-- The MAILING DATE of this communication appears n the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-13,16-18,21-24 and 27-148 is/are pending in the application.
- 4a) Of the above claim(s) 31-143 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-13,16-18,21-24,27-30 and 144-148 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,9,10,15.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 9/3/03 has been entered.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 10/22/01, 12/16/02, 1/30/03 and 9/3/03 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 2-13, 16-18, 21-24, 27-30, and 144-148 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for three compounds, see page 102, does not reasonably provide enablement for trillions of compounds as claimed. The specification does not enable any person skilled in the art

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to which it pertains, or with which it is most nearly connected, to make trillions of compounds and practice the invention commensurate in scope with these claims.

With regards to the rejection under 35 USC 112, first paragraph, the following factors have been carefully considered. (In re Wands, 8 USPQ2d 1400, 1404(CAFC 1988)).

- a) Breadth of the claims,
- b) Nature of the invention,
- c) Level of ordinary skill in the art,
- d) Level of predictability in the art,
- e) Amount of direction and guidance provided by the inventor,
- f) Working examples,
- g) Level of experimentation needed to make or use the invention based on the

content of the disclosure.

a) Claims are directed to compounds and composition, wherein the broad generic formula (XV) of claim 148, which covers 16 pages and billions of compounds. The disclosure is not seen to provide sufficient guidance which would enable one of ordinary skill in the art to make and use the compounds as claimed herein, especially, when only three compounds have been made, see page 102, which is certainly not the representative of the billions of compounds claimed herein. The metes and bounds of the are not clearly set forth, i.e. to say that it is not clear as to how many compounds can be made and how can they be made, and how can they be practiced.

b). The nature of the invention is determined by the state of the prior art.

Compounds used for treating Alzheimer's disease, are having different chemical structure, when all possible substituents are contemplated, and they certainly will have different chemical properties, absent evidence to the contrary. The prior art is silent with regard to the variety of compounds asserted to be useful for treating Alzheimer's

disease. The identity of the compounds which are derived having any heterocyclyl substituent, and amount of composition required to treat the disease is not addressed in the instant disclosure.

c). The level of ordinary skill in the art of formulating the pharmaceutical composition for treating the Alzheimer disease is considered to be relatively high. Those responsible for formulating procedural steps involving the relative amount of the composition depending on the chemical nature of the compound would be individual with very high credentials and minimally at least various years of actual hand on experience.

d). The level of predictability in the art is considered by the examiner to be high. Treatment of Alzheimer's disease using billions of compounds derived from the broad generic claimed subject matter are recognized as unpredictable. If these were predictable art, one would be able to predict as to which of the compounds as well as the effective amount of the compounds can be used for treating the disease.

e). The amount of direction provided by the instant disclosure is determined by the teachings set forth in the instant specification, including the working examples. The specification is limited to the three examples on page 102, without any further guidance. The specification does not provide teachings, which would direct the skilled artisan in procedures, which would include the use of billions of compounds, their effective amount for treating the disease.

f). The level of experimentation necessary to make and use the instant invention with compounds as claimed herein is seen to be undue in the instant case. It would

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indeed require undue experimentation to determine the identity of the appropriate compound, their effective amount for treating the Alzheimer's disease. There are just three compounds made in the instant specification, and that too, without any effective amount suggested for treating the disease. A chemically and structurally divergent compound, for example having a morpholino substituent, can not reasonably be predicted to behave in a manner such that it is possible to make and use the instant claimed invention, based on three examples when the art is silent with regard to interchangeability or the correlative chemical and physical properties of the compounds asserted to be useful in treating the incredible disease.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 2-13, 16-18, 21-24, 27-30 and 144-148 are provisionally rejected under the judicially created doctrine of double patenting over claims 1-34 of copending Application No. 10/160,777. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.


The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: R1, R2, R3, Rc, R20, and R_N of the above application extensively overlap the corresponding definition of the instant application.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHAILENDRA - KUMAR whose telephone number is 703-308-4519. The examiner can normally be reached on Mon-Thur 8:00-5:30, Alt Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 703-308-4532. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


SHAILENDRA - KUMAR
Primary Examiner
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S.Kumar
10/21/03